REMARKS

Support for new claims 16-19 can be found for example in the specification at page 13 line 1 to page 17, line 25. The compounds on page 15 of the specification contained an obvious translational error (i.e, harnstoff is the German word for urea). The specification has been amended accordingly. No new matter has been added.

Double Patenting Rejection

Applicants wish to defer addressing the provisional obviousness-type double patenting rejections over claims 75 and 76 of co-pending application 10/516,745 and claims 40-45 of co-pending application 10/547,746, until such time as the alleged conflicting claims have been allowed.

Rejection under 35 U.S.C. § 112

Applicants respectfully traverse the rejection of claims under 35 U.S.C. §112, as allegedly lacking adequate written description and for allegedly being non-enabled.

On page 6 of the Office Action, the Examiner alleges that the mere fact that the Applicant may have discovered one type of drug to be a substance that modulates SGK1 is not sufficient to claim the entire genus. On page 8 and 9 of the Office Action, the Examiner alleges that the claims are not enabled.

Applicants' instant claims are directed to a method of altering insulin secretion comprising, contacting a pancreatic islet cell expressing SGK1 with a substance that modulates SGK1. Applicants' specification teaches a skilled worker that high dose Glucocorticoid treatment over an extended time period predisposes to the development of diabetes mellitus at least in part through impairment of insulin secretion. The underlying mechanism has previously remained elusive and targets that would allow therapeutic intervention were unknown. Applicants' specification not only defines a new mechanism and molecular target but at the same time teaches *how* to identify new compounds that interfere with the mechanism with the aim to overcome diabetes mellitus. The instant specification and the reference publications cited therein establish numerous assay systems that can be used to

measure glucocorticoid inducible kinase SGK1 activity, such as, for example, the scintillation proximity assay (Sorg et al., J. of. Biomolecular Screening, 2002, 7, 11-19) and flashplate assay in which the radioactive phosphorylation of a protein or peptide as substrate with gamma ATP will be measured. Furthermore, the specification teaches that homogeneous time-resolved fluorescence resonance energy transfer (HTR-FRET), and fluorescence polarization (FP) technologies are useful assay methods (Sills et al., J. of Biomolecular Screening, 2002, 191-214). Additionally, the specification teaches other non-radioactive ELISA based assay methods which use specific phospho-antibodies (AB).

The instant application additionally provides a cell culture system for the measurement of insulin secretion. See, for example, the disclosure contained in Example 2.

Applicants' specification further provides express written description of numerous compounds (five pages) which can be used to alter insulin secretion.

It is now well-settled that a specification need not disclose, and preferably omits, what is well known to those skilled in the art when an application is filed. See, e.g., *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987). See, also, MPEP §2164.05(a) and *Capon v. Eshhar v. Dudas*, (Fed. Cir. 2005) 418 F.3d 1349, 76 U.S.P.Q.2d 1078. Likewise, in the instant application, the specification need not provide express guidance with respect to individual species that are commensurate with Applicants' claims so long as such species can be determined by the numerous assays disclosed within Applicants specification.

Therefore, view of the aforementioned arguments, it is courteously submitted that Applicants' claims in the current form, with adequate support from the instant specification and the references cited therein, fully conform to the written description requirement as stated in the PTO's own guidelines.

Furthermore, Applicants' specification has provided a skilled worker with guidance on how to determine other compounds that modulate SGK1 and which are effective in altering insulin secretion and disease associated with insulin secretion.

Thus, Applicants' specification, in view of the disclosure and references cited therein, provides more than sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention with an effort that is no more than routine with in the art.

Withdrawal of the all the rejections, and passage to allowance is courteously requested.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues that could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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